APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/497,943	02/04/00	BEHLKE	M 7614-018-999

EXAMINER
SISSON,B

ART UNIT	PAPER NUMBER
1655	

HM22/0912

Pennie & Edmonds LLP
1155 Avenue of the Americas
New York NY 10036-2711

DATE MAILED:
09/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/497,943	Applicant(s) BEHLKE ET AL.
	Examiner Bradley L. Sisson	Art Unit 1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _1_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1) ☐ Responsive to communication(s) filed on _____ .

2a) ☐ This action is **FINAL**.   2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) _1-54_ is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims _1-54_ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

    a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:

      1. ☐ received.

      2. ☐ received in Application No. (Series Code / Serial Number) _____ .

      3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .

18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☒ Other: *Notice to Comply* .

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14, drawn to a complex, classified in class 536, subclass 24.32; and claims 15-28, drawn to a reaction mixture, classified in class 536, subclass 23.1.

II. Claims 29-48, drawn to a method of labeling nucleic acid, classified in class 435, subclass 91.1; claims 49 and 50, drawn to a method of detecting a target nucleic acid in a sample, and claims 51-54, drawn to a related kit, all classified in class 436, subclass 94.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid in the complex can be used in a method of cloning as opposed to a method of labeling.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5.   Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Sequence Rules

6.   This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

7.   Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Conclusion

8.   Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

       If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bradley L. Sisson
Primary Examiner
Art Unit 1655

BLS
August 23, 2000

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821 – 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 CFR 1.821–1.825. Applicant's attention is directed to these regulations, published at 114 OC 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).

☑ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of th marked-up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).

☐ 7. Other: ——————————————————————————————

Applicant must provide:

☑ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing"

☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification

☑ A statement that the content of the paper and computer readable copies are the sar and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d)

For questions regarding compliance with these requirements, please contac

For Rules Interpretation, call (703) 308-1123
For CRF submission help, call (703) 308-4212
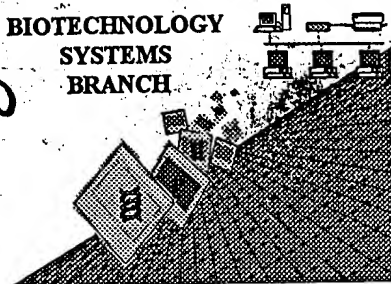For PatentIn software help, call (703) 557-0400

Please return a copy of this notice with your response.

RAW SEQUENCE LISTING ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following CRF diskette:

Application Serial Number: *09/497,943*

Art Unit / Team No. : *OIPE*

Date Processed by STIC: *2/29/2000*

THE ATTACHED PRINTOUT EXPLAINS THE ERRORS DETECTED.

PLEASE BE SURE TO FORWARD THIS INFORMATION TO THE APPLICANTS BY EITHER:

1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANTS ALONG WITH A NOTICE TO COMPLY or,

2) CALLING APPLICANTS AND FAXING THEM A COPY OF THE PRINTOUT WITH A NOTICE TO COMPLY

THIS WILL INSURE THAT THE NEXT SUBMISSION RECEIVED FROM THEM WILL BE ERROR FREE.

IF YOU HAVE ANY FURTHER QUESTIONS, PLEASE CALL:

MARK SPENCER 703-308-4212

Raw Sequence Listing Error Summary

ERROR DETECTED   SUGGESTED   CORRECTION   SERIAL NUMBER: _09/497,943_

ATTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE

1 _____ Wrapped Nucleics   The number/text at the end of each line "wrapped" down to the next line.
This may occur if your file was retrieved in a word processor after creating it.
Please adjust your right margin to .3, as this will prevent "wrapping".

2 _____ Wrapped Aminos   The amino acid number/text at the end of each line "wrapped " down to the next line.
This may occur if your file was retrieved in a word processor after creating it.
Please adjust your right margin to .3, as this will prevent "wrapping".

3 _____ Incorrect Line Length   The rules require that a line not exceed 72 characters in length. This includes spaces.

4 _____ Misaligned Amino Acid Numbering   The numbering under each 5th amino acid is misaligned. This may be caused by the use of tabs
between the numbering. It is recommended to delete any tabs and use spacing between the numbers.

5 _____ Non-ASCII   This file was not saved in ASCII (DOS) text, as required by the Sequence Rules.
Please ensure your subsequent submission is saved in ASCII text so that it can be processed.

6 _____ Variable Length   Sequence(s) _____ contain n's or Xaa's which represented more than one residue.
As per the rules, each n or Xaa can only represent a single residue.
Please present the maximum number of each residue having variable length and
indicate in the (ix) feature section that some may be missing.

7 _____ PatentIn ver. 2.0 "bug"   A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid
sequence(s) _____. Normally, PatentIn would automatically generate this section from the
previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section
to the subsequent amino acid sequence.

8 _____ Skipped Sequences (OLD RULES)   Sequence(s) _____ missing. If intentional, please use the following format for each skipped sequence:
(2) INFORMATION FOR SEQ ID NO:X:
(i) SEQUENCE CHARACTERISTICS:(Do not insert any headings under "SEQUENCE CHARACTERISTICS")
(xi) SEQUENCE DESCRIPTION:SEQ ID NO:X:
This sequence is intentionally skipped

Please also adjust the "(iii) NUMBER OF SEQUENCES:" response to include the skipped sequence(s).

9 _____ Skipped Sequences (NEW RULES)   Sequence(s) _____ missing. If intentional, please use the following format for each skipped sequence.
<210> sequence id number
<400> sequence id number
000

10 _____ Use of n's or Xaa's (NEW RULES)   Use of n's and/or Xaa's have been detected in the Sequence Listing.
Use of <220> to <223> is MANDATORY if n's or Xaa's are present.
In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.

11 _____ Use of <213>Organism (NEW RULES)   Sequence(s) _____ are missing this mandatory field or its response.

12 _____ Use of <220>Feature (NEW RULES)   Sequence(s) _____ are missing the <220>Feature and associated headings.
Use of <220> to <223> is MANDATORY if <213>ORGANISM is "Artificial" or "Unknown"
Please explain source of genetic material in <220> to <223> section.
(See "Federal Register," 6/01/98, Vol. 63, No. 104, pp. 29631-32)   (Sec. 1.823 of new Rules)

13 _____ PatentIn ver. 2.0 "bug"   Please do not use "Copy to Disk" function of PatentIn version 2.0. This causes a corrupted
file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing).
Instead, please use "File Manager" or any other means to copy file to floppy disk.

AKS-Biotechnology Systems Branch- 5/15/99

This Raw Listing contains the General Information Does Not Comply
Section and up to first 5 pages.   Corrected Diskette Need

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 1    <110> APPLICANT: Behlke, et al.
 2    <120> TITLE OF INVENTION: PRIMER EXTENSION METHODS FOR PRODUCTION OF HIGH
 3          SPECIFIC ACTIVITY NUCLEIC ACID PROBES
 4    <130> FILE REFERENCE: 7614-018
 5    <140> CURRENT APPLICATION NUMBER: US/09/497,943
 6    <141> CURRENT FILING DATE: 2000-02-04
 7    <160> NUMBER OF SEQ ID NOS: 25
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